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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/829,006	04/21/2004	Eduardo Gomez-de-Diego	34970	5508
7590 12/12/2006			EXAMINER	
Henry Estevez			LEWIS, KIM M	
ALLEN, DYER, DOPPELT, MILBRATH & GILCHRIST, P.A. Suite 1401		ART UNIT	PAPER NUMBER	
255 So. Orange Ave.			3772	

Please find below and/or attached an Office communication concerning this application or proceeding.

		Application No.	Applicant(s)			
Office Action Summary		10/829,006	GOMEZ-DE-DIEGO, EDUARDO			
		Examiner	Art Unit			
		Kim M. Lewis	3772			
The MAILING DATE of this communication appears on the cover sheet with the correspondence address Period for Reply						
A SHORTENED S WHICHEVER IS I - Extensions of time marafter SIX (6) MONTHS - If NO period for reply it - Failure to reply within I Any reply received by	STATUTORY PERIOD FOR REPLY ONGER, FROM THE MAILING DAY be available under the provisions of 37 CFR 1.15 from the mailing date of this communication is specified above, the maximum statutory period whe set or extended period for reply will, by statute the Office later than three months after the mailing ustment. See 37 CFR 1.704(b).	ATE OF THIS COMMUNICATION 36(a). In no event, however, may a reply be tim will apply and will expire SIX (6) MONTHS from a cause the application to become ABANDONE!	J. nely filed the mailing date of this communication. D (35 U.S.C. § 133).			
Status						
2a) This action 3) Since this a	to communication(s) filed on is FINAL 2b)⊠ This pplication is in condition for allowar cordance with the practice under E	action is non-final. nce except for formal matters, pro	·			
Disposition of Claims						
4a) Of the a 5) ☐ Claim(s) 6) ☑ Claim(s) <u>1-</u> 7) ☐ Claim(s)	37 is/are pending in the application bove claim(s) is/are withdraw is/are allowed. 37 is/are rejected is/are objected to are subject to restriction and/o	vn from consideration.				
Application Papers						
9)☐ The specification is objected to by the Examiner.						
10)☐ The drawing(s) filed on is/are: a)☐ accepted or b)☐ objected to by the Examiner.						
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).						
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d). 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.						
Priority under 35 U.S	S.C. § 119		,			
12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f). a) All b) Some * c) None of: 1. Certified copies of the priority documents have been received. 2. Certified copies of the priority documents have been received in Application No 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)). * See the attached detailed Office action for a list of the certified copies not received.						
	on's Patent Drawing Review (PTO-948) ire Statement(s) (PTO/SB/08)	4) Interview Summary Paper No(s)/Mail Do 5) Notice of Informal F 6) Other: Detailed Acti	ate Patent Application			

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DETAILED ACTION

Drawings

The drawings are objected to because Fig. 3 should be enclosed in brackets 1. since it is an exploded view that appears on the same page as another figure. Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Specification

2. The disclosure is objected to because of the following informalities:

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Page 6, line 2, "therin" should read --therein--; and

Page 7, line 6, the specification recites "an outer, relatively soft retaining member 15a", then on lines 8-9, the specification recites "a tubular outer member 15a".

Appropriate correction is required.

Claim Objections

3. Claim 2 is objected to because of the following informalities: Claim 2, line 1, after "wherein" insert --the--. Appropriate correction is required.

Claim Rejections - 35 USC § 112

4. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5. Claim 4 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. More specifically, it is unclear from the specification and claim 4 as to how the angle of connection between the base member and the base member connector is adjusted. Thus, it is unclear how to make and use the invention.

Claim Rejections - 35 USC § 102

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

- (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
- 7. Claims 1-5, 7, 9-15, 19-23, 25, 27, 29-32, 36 and 37 are rejected under 35 U.S.C. 102(b) as being anticipated by WO 96/26691 ("Siana").

As regards claim 1, Slana discloses a method and apparatus for stretching the penis that anticipates applicant's presently claimed invention. More specifically, as can be seen in Fig. 1, Siana discloses an apparatus for applying traction (note the abstract) to a patient's penis having a shaft, a glans, and a corona glandis, the apparatus comprising: at least one base member (1) as shown in Figs. 1 and 4, having a generally arcuate periphery of sufficient dimension for the patient to insert the penis in the apparatus; at least one base member connector (3) positioned on said at least one base member; a plurality of extension members (11, 12) connected with said at least one base member connector and extending distally therefrom; at least one support member (20)connected with said plurality of extension members and thereby being distally spaced apart from said at least one base member, said at least one support member having a surface thereon for supporting the penis (see Figs. 6 and 7); and a retaining collar connected to said at least one support member adjacent said support surface and positioned so as to at least partially encircle the shaft of the penis thereby securing the

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distal penis to the support member (note strap 24 disclosed on page 10, line 33-page 11, line 14 and band 4).

As regards claim 2, Siana discloses the apparatus of claim 1, wherein generally arcuate periphery of said at least one base member is approximately complementary to a pubic mound (note page 8, lines 18-27).

As regards claim 3, Siana discloses the apparatus of claim 1, wherein the plurality of base member connectors comprises connectors extending outwardly from the generally arcuate periphery of said at least one base member and is approximately perpendicular to an imaginary diameter thereof (note Fig. 1)

As regards claim 4, Siana discloses the apparatus of claim 1, wherein said at least one base member connector comprises a hinged connector (2) extending outwardly from the generally arcuate periphery of said at least one base member so that an angle of connection of said at least one base member connector to the at least one base member may be adjusted (note page 10, lines 13-18 and Fig. 3).

As regards claim 5, Siane discloses the apparatus of claim 1, wherein said at least one base member connector comprises a knob (member 10 is a knob) having a threaded connector engaged with a complementary threaded piston, said piston being slidably disposed within a cylinder at a first cylinder end, said cylinder having therein a biasing member urging against said piston, and having at a second cylinder end threads complementary to at least one individual extension member of said plurality of extension members (note page 8, line 29-page 9, line 3 and Fig. 2).

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As regards claim 7, note that connecting members (11 and 12) are threadingly connectable to each other via threads (13) and (14).

As regards claim 9, Siane discloses the apparatus of claim 1, wherein said plurality of extension members comprises a sufficient number of individual extension members to extend said apparatus to apply traction to the patient's penis by increasing distance between said at least one base member and said retaining collar (note the abstract which discloses length adjustment).

As regards claim 10, Siane discloses at page 8, lines 4-7, that "the elastic band 4 is attached around the penis by means of a closing mechanism consisting of two hooks 7 so that the inside diameter of the band may be adapted to the thickness of the penis". Thus, the support member is curved since it is wrapped around the penis.

As regards claim 11, note Fig.1, which discloses the inside diameter of band (4) as being substantially the same as the imaginary diameter of base member (1).

Regarding claim 12, as can be seen from Figs. 6 and 7, Siana discloses the apparatus of claim 1, wherein said at least one support member comprises first and second ends and a curved surface therebetween, said first and second ends spaced apart a distance approximately equal to an imaginary diameter of the arcuate periphery of said at least one base member.

As regards claim 13, note openings (23).

As regards claim 14, note strap (24) and band (4).

As regards claim 15, band (4) comprises elastic and silicone (note page 10, line 33 –page 11, line 14).

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As regards claim 19, note the rejection of claim 1. In further regard to claim 19, note retaining collar (band 4 or strap 24) and the left side and right side base member connectors (3).

As regards claim 20, note the rejection of claim 2.

As regards claim 21, note Fig. 4, which discloses the annular base member and Fig. 1, which discloses connectors (3) being perpendicular to the imaginary diameter of the base member.

As regards claim 22, note the rejection of claim 4 above.

As regards claim 23, note the rejection of claim 5 above.

As regards claim 25, note the rejection of claim 7 above.

As regards claim 27, note the rejection of claim 9 above.

As regards claim 29, note the rejection of claim 11 above.

As regards claim 30, note the rejection of claim 13 above.

As regards claim 31, note the rejection of claim 14 above.

As regards claim 32, note the rejection of claim 15 above.

As regards claim 36, the method of applying traction to a patient's penis is practiced by mere use of the Siana apparatus as discussed in the rejection of the claims above.

As regards claim 37, note the abstract, which discloses the use of the traction device on a penis for an extended period of time.

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Claim Rejections - 35 USC § 103

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

- (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.
- 9. The factual inquiries set forth in *Graham* v. *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:
 - 1. Determining the scope and contents of the prior art.
 - 2. Ascertaining the differences between the prior art and the claims at issue.
 - 3. Resolving the level of ordinary skill in the pertinent art.
 - 4. Considering objective evidence present in the application indicating obviousness or nonobviousness.
- 10. Claims 6, 8, 16-18, 24, 26 and 33-35 are rejected under 35 U.S.C. 103(a) as being unpatentable over Siane.

As regards claim 6, Siane fails to teach the apparatus of claim 1, wherein said plurality of extension members comprises individual extension members having different lengths. Instead, Siane teaches an equivalent configuration including adjustment means, which allows length adjustment of the connectors in order to properly size the apparatus. Thus, since the applicant fails to state in the specification that different length connectors are critical, it would have been an obvious design choice to one having ordinary skill in the art to use any known equivalent in order to adjust the length of the connectors in order to properly size the apparatus to the individual user.

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As regards claim 8, Siane fails to teach the apparatus of claim 1, wherein said plurality of extension members threadingly connects to said at least one base member to said at least one support member. As can be seen from Fig. 7, Siane discloses other connection means. Absent a critical teaching and/or a showing of unexpected results derived from threadingly connecting said at least one base member to said at least one support member, the examiner contends that the type of connection is an obvious design choice which does not patentably distinguish applicant's invention.

Thus, it would have been an obvious design choice to one having ordinary skill in the art to connect said at least one base member to said at least one support member using any well known connection.

As regards claim 16-18, Siana fails to disclose the apparatus of claim 1, wherein said retaining collar comprises a tubular outer member and an elastic inner member extending therethrough, wherein said elastic inner member has a first end and a second end, both of which protrude from said tubular outer member, and wherein said retaining collar is secured to said at least one support member by adjustably connecting the protruding first and second ends to the at least one support member.

Instead, Siana disclose two different types of retaining collars. One is an elastic band (4) having an interior coating of silicone (page 8, lines 9-12). The other is a strap (24) constructed from flexible material, such as, for example, silicone (page 10, line 36-page 11, line 2). Both of the retaining collars have first and second ends, each connected to the support member.

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These two retaining collars serve the same purpose as the retaining collar of the instant invention. Applicant has not provided the office with unexpected results showing

the advantages of the retaining collar comprising a tubular outer member and an elastic

inner member extending therethrough. Thus, the office concludes that this configuration

is an obvious design choice, which does not patentably distinguish applicant's invention.

As such, it would have been an obvious design choice to one having ordinary skill in the

art to select any style of retaining collar to retain the penis as long as the retaining collar

softly engages the penis and does not externally damage the penis.

As regards claim 24, note the rejection of claim 6 above.

As regards claim 26, note the rejection of claim 8 above.

As regards claims 33-35, note the rejection of claims 16-18 above.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kim M. Lewis whose telephone number is (571) 272-4796. The examiner can normally be reached on Monday to Friday, from 8:30 am to 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Patricia Bianco, can be reached on (571) 272-4940. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 57/1-272-1000

Kim M. Lewiś Primary Examiner Art Unit 3772

kml December 1, 2006